Vancomycin 500mg and 1000mg
Powder for Concentrate for Solution for Infusion

Read all of this leaflet carefully before you start using this medicine.

1. What Vancomycin powder is and what it is used for
2. How to use Vancomycin powder
3. Possible side effects
4. How Vancomycin powder is stored
5. Further information

1. What Vancomycin powder is and what it is used for
Vancomycin powder is a reconstituted concentrate containing 50mg/ml vancomycin. Injections of the reconstituted solution are for intravenous injection. Dissolve the content of each 1000mg vial in 20ml of sterile water for injections.

2. How to use Vancomycin powder
Intravenous use. For intravenous use the powder must be reconstituted and the resulting concentrate may then be immediately diluted further prior to use.

3. Possible side effects
Do not have Vancomycin powder if you:

- are allergic to vancomycin hydrochloride or to any of the other ingredients of Vancomycin powder (See Section 6 for a list of ingredients).

4. How Vancomycin powder is stored
Tell your doctor if you have had any problems with this medicine or any other medicine you have been taking.

5. Further information

Preparation of the reconstituted concentrate
Dissolve the content of each 1000mg vial in 20ml of sterile water for injection. Concentrate

Preparation of final diluted Solution for infusion
Reconstituted concentrate containing 10mg/ml vancomycin should

Continuous next page

Vancomycin powder for infusion 500mg & 1000g PIL - UK

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Tell your doctor if you have had any problems with this medicine or any other medicine you have been taking.

5. Further information

Preparation of the reconstituted concentrate
Dissolve the content of each 1000mg vial in 10ml of sterile water for injection. Dissolve the content of each 1000mg vial in 20ml of sterile water for injection.

Preparation of final diluted Solution for infusion
Reconstituted concentrate containing 15mg/ml of vancomycin should not exceed 5mg/ml. The desired dose should be administered slowly by intravenous infusion at a rate of no more than 10mg/min, for at least 60 minutes or even longer.

Before administration, the reconstituted and diluted solutions should be inspected visually for particulate matter and discoloration. Only clear and colourless to pale yellow solution free from particles should be used.


Vancomycin powder for solution for infusion 500mg & 1000g PIL - UK

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Devised by: DR

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How to use Vancomycin powder

Vancomycin powder can be given to you by hospital staff, using an infusion. (a slow injection by means of a drip). Each infusion will be given slowly, usually lasting for at least one hour. It may also be given to you to drink or via a tube in your nose.

How much you will receive

The dose of Vancomycin powder your doctor gives you will depend on your age, weight, general health condition, the severity of the illness, whether you have been taking other medicines and how well you respond to the treatment.

For patients whose kidneys are working normally

Adults and children over 12 years of age: the usual intravenous dose is 15mg per kg bodyweight per 24 hours. It is given every 6 hours (or every 12 hours).

Children: from one month to 12 years of age: the usual intravenous dose is 15mg per kg bodyweight given every 12 hours (total daily dosage not to exceed 1g).

New born babies (full term):

• 0 - 6 days old: starting dose of 15mg for each kilogram of the child's weight, followed by 15mg per kilogram every 12 hours.
• 7-10 days old: starting dose of 15mg for each kilogram of the child's weight, followed by 15mg per kilogram every 8 hours.

For patients whose kidneys are not working normally

The doctor will reduce the dose or extend the interval between two doses.

Special tests will be carried out and the dose will be adjusted to meet the needs of the patient.

If you are elderly, 65 years of age and over, your doctor will also consider how your kidneys are likely to be working.

For patients whose liver is not working normally

If you have severe liver damage, special tests will be carried out and the dose will be adjusted to meet the needs of the patient.

For patients whose kidneys do not work at all

The starting dose is 15mg for each kilogram of bodyweight, followed by a maintenance dose of approximately 15mg for each kilogram of bodyweight, every 24 hours.

Oral doses

Adults and elderly: 100mg a day in divided doses for 7-10 days.

Children: maximum daily dose of 2000mg.

Your doctor will decide when your treatment should end.

If you receive too much Vancomycin

• Tell your doctor at once if you think you have received a larger dose than you were prescribed. The consequences could become very serious, so tell your doctor or nurse immediately.

• Vancomycin may cause a serious or life-threatening allergic reaction that may affect your skin or other parts of your body such as your eyes or blood cells (DRESS syndrome). Symptoms include skin rash, fever, swollen glands that do not go away, swelling of your lips and tongue, yellowing of your skin or the whites of the eyes, unusual bleeding or bruising, low blood pressure, fever, or blue or gray appearance of your skin or body. Symptoms may begin 2 to 5 days after you begin treatment but may start later.

• If you have any further questions about receiving this medicine, please ask your doctor.

Possible side effects

Side effects of medicines can cause side effects, although not everybody gets them.

• Contact your doctor at once if the following effects happen swelling of your face, lips, tongue, or throat causing difficulty in breathing, feeling faint, skin rash.

The consequences could become very serious, so tell your doctor or nurse immediately.

• Vancomycin may cause a serious or life-threatening allergic reaction that may affect your skin or other parts of your body such as your eyes or blood cells (DRESS syndrome). Symptoms include skin rash, fever, swollen glands that do not go away, swelling of your lips and tongue, yellowing of your skin or the whites of the eyes, unusual bleeding or bruising, low blood pressure, fever, or blue or gray appearance of your skin or body. Symptoms may begin 2 to 5 days after you begin treatment but may start later.

• If you have any further questions about receiving this medicine, please ask your doctor.

Tell your doctor or pharmacist if the following side effects occur or get worse:

• Common side effects (affect 1 to 10 users in 100):

  - shortness of breath
  - nausea
  - diarrhea
  - dizziness
  - skin reactions such as rash, swelling, itching or hives

• Rare side effects (affect less than 1 user in 10,000):

  - blood in your urine
  - low blood pressure
  - shortness of breath; noisy breathing (stridor)
  - skin reactions such as red rash, itching, rashes, swelling of the area around your vein
  - redness and swelling at the point where the injection went into your body

• Uncommon side effects (affect less than 1 user in 1000):

  - dizziness
  - changes to the number of various types of white blood cells in the blood
  - changes to the number of various types of red blood cells in the blood

• Infections of the kidneys

• Acute kidney failure

• Acute glomerular filtration failure

Vancomycin powder is a freeze-dried, off-white powder. It is vacuum-packed in a glass container with a rubber and aluminum seal and should be stored cool.

Pack sizes:

1 vial in a carton

How Vancomycin powder is stored

Keep out of the reach of and not accessible to children.

Do not use Vancomycin powder after the expiry date which is stated on the carton and vial after EXP. The expiry date refers to the last day of that month.

Keep the vial in the outer carton in order to protect from light.

Store before 25°C.

Medicines should not be disposed of via a wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Further information

What Vancomycin powder contains

The active substance in Vancomycin powder is vancomycin hydrochloride. The following additional substances may be present: sodium hydroxide, hydrochloric acid.

What Vancomycin powder looks like and the contents of the pack

Vancomycin powder is a freeze-dried, off-white powder. It is vacuum-packed in a glass container with a rubber and aluminum seal and should be stored cool.

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1 vial in a carton

Marketing Authorisation Holder:

Actavis Group PTC ehf., Reykjavikurgarður 76-78, 102 Reykjavikur, Iceland

Manufacturers:

Alpeci, Płocka Sp. z o.o., 16, Daniszewska Str. 22, 80-290 Warsaw Poland

Actavis Group PTC ehf., Reykjavikurgarður 76-78, 102 Reykjavikur, Iceland

This leaflet was last revised in October 2013.

If you would like a leaflet with larger text, please contact 01271 311257.

Vancomycin Powder for solution for infusion 500mg & 1000g PIL - UK

ITEM NUMBER: 4542044 (AAAG0244)

Weight (kg) x (140 - age (years))

If the creatinine clearance is not available, the following nomogram can be applied to calculate the creatinine clearance from the patient’s age, sex and serum creatinine.

Men

Weight (kg) x age (years) x body surface area (m²)

Women

0.85 x value calculated by the above formula.

Actavis, Barnstaple, EX32 8NS, UK

100x102

AAAAG244

Shelf life of diluted product:

Shelf-life of reconstituted concentrate:

Chemical and physical in-use stability of the diluted product has been demonstrated for 48 hours at both 2-8°C and 25°C when diluted with either 0.9% sodium chloride or 5% glucose.

If the creatine clearance is not available, the following formula may be used to calculate the creatinine clearance from the patient’s age, sex and serum creatinine.

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Weight (kg) x age (years) x body surface area (m²)

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Shelf life of reconstituted concentrate:

The reconstituted concentrate should be diluted immediately after preparation.

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